K022723

DEC 2 6 2002

SECTION 11

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared;

a. Applicant:

Mastel Precision, Inc.
2843 Samco Road, Suite A
Rapid City, SD 57702
(605) 341-4595

b. Contact Person:

Maureen Weiner
Regulatory Consultant to Mastel Precision, Inc.
53 Barcelona
Irvine, CA 92614
(949) 757-0755

Maureen Weiner

c. Date Summary Prepared: December 17, 2002

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: Mastel 1 Folder™ Implantation System

b. Classification Name: Intraocular Lens Guide

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	Allergan, Inc.
Device:	AMO PhacoFlex II Insertion System
510(k):	K961242
Date Cleared:	June 17, 1996

Company:	Alcon Research, Ltd.
Device:	Monarch II IOL Delivery System
510(k):	K001157
Date Cleared:	June 27, 2000

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The Mastel 1 Folder is an ophthalmic surgical device designed for use in inserting a foldable intraocular lens into the eye. The materials, basic scientific concepts, physical properties and intended use of the Mastel 1 Folder are similar to those of the predicate devices.

The Mastel 1 Folder Implantation System is comprised of a medical-grade titanium handpiece, a material commonly used in reusable surgical devices. The handpiece rod is designed to accept a single-use cartridge. The handpiece is reusable and is designed to withstand conventional in-office steam autoclaving. The handpiece is provided to the customer in a plastic case in a non-sterile state.

5. Statement of intended use:

The Mastel 1 Folder™ Insertion System is intended to fold and assist in inserting the SENSAR™, model AR40e intraocular lens, ONLY into the capsular bag.

5. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

Comparison of Devices for Substantial Equivalence

CHARACTERISTICS	Mastel Precision Mastel 1 Folder Implantation System	Allergan AMO PhacoFlex II Insertion System	Alcon Monarch II IOL Delivery System
Indication for use	To fold and assist in inserting the SENSAR, model AR40e intraocular lens, ONLY into the capsular bag	To fold and assist in inserting the AMO PhacoFlex II (SLM-2/UV) family of intraocular lenses, specifically the SI-30NB and SI-40NB, into the eye	To fold and deliver Alcon ACRYSOF intraocular lenses into the eye for replacement of the human crystalline lens
Operating Principle	The handpiece delivers the loaded IOL into the eye	IOL is loaded into the cartridge and the IOL is pushed through the cartridge and delivered into the eye	The handpiece accepts the cartridge (loaded with the IOL) and delivers the IOL by using a plunger to express the lens into the eye
Patient Contact Portion of Device	No patient contact	Cartridge contacts eye, cartridge material is polypropylene	Cartridge contacts eye, cartridge material is polypropylene
Handpiece Material	Titanium	Titanium	Titanium
Reusable/Disposable	Reusable	Reusable	Reusable
Handpiece Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile

7. Brief summary of nonclinical tests and results:

In vitro performance testing was conducted on the Mastel 1 Folder Insertion System. The intraocular lenses (IOLs) were delivered using the Mastel 1 Folder handpiece and then evaluated for diopter, astigmatism, resolution, visual acuity, overall diameter, loop angles, and sagitta. The results revealed that all Mastel 1 Folders provided acceptable results when delivering 130 intraocular lenses, ranging from 6.0 D to 23.0 D.

Based on the performance testing, Mastel Precision concludes that this system is a safe and effective device for folding and assisting in inserting the SENSAR™, model AR40e intraocular lens into the eye.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 6 2002

Mastel Precision Inc.
c/o Maureen Weiner
Regulatory Affairs Consultant
53 Barcelona
Irvine, CA 92614

Re: K022723
Trade/Device Name: Mastel 1 Folder™ Implantation System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I
Product Code: KYB
Dated: December 17, 2002
Received: December 18, 2002

Dear Ms. Weiner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K022723

Device Name: Mastel 1 Folder™ Implantation System

Indications for Use:

The Mastel 1 Folder™ Implantation System is intended to fold and assist in inserting the SENSAR™, model AR40e intraocular lens, ONLY into the capsular bag.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joel P. Glover

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K022723

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)